UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,690	01/09/2001	Orville G. Kolterman	030639.0066.UTL	4666
Intellectual Property Department Amylin Pharmaceuticals, Inc.		9	EXAM	IINER
			JIANG, DONG	
	9360 Towne Centre Drive San Diego, CA 92121	ART UNIT	PAPER NUMBER	
			1646	
			MAIL DATE	DELIVERY MODE
			10/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

RECORD OF ORAL HEARING
UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ORVILLE G. KOLTERMAN
and ANDREW A. YOUNG
Application 00/756 600
Application 09/756,690 Technology Center 1600
Oral Hearing Held: September 17, 2009
Before LORA M. GREEN, RICHARD M. LEBOVITZ, and
FRANCISCO C. PRATS, Administrative Patent Judges.
APPEARANCES:
ON BEHALF OF THE APPELLANTS:
DAVID R. MARSH
555 12th Street, N.W.
Washington, D.C. 20004
The above-entitled matter came on for hearing Thursday,
September 17, 2009, commencing at 9:10 a.m., at the U.S. Patent and
Trademark Office, 600 Dulany Street, Alexandria, Virginia, before
Sussy E. Morehouse, Notary Public.

1	<u>PROCEEDINGS</u>
2	THE USHER: Calendar No. 57, Mr. Marsh.
3	JUDGE GREEN: Good morning.
4	MR. MARSH: Good morning, Your Honors.
5	JUDGE GREEN: Good morning, Mr. Marsh. As you can see, we
6	have Examiner Jiang here to argue, right?
7	EXAMINER SPECTOR: Examiner Jiang and Examiner Spector. I
8	was the primary at the time.
9	JUDGE GREEN: So you can have 20 minutes.
10	MR. MARSH: Sure.
11	JUDGE GREEN: And you can reserve five minutes, if you would
12	like, for rebuttal.
13	MR. MARSH: Can I reserve 10 minutes, depending on how the
14	questions that come from the judges?
15	JUDGE GREEN: That should be fine. Thank you.
16	MR. MARSH: Thank you. I think sorry.
17	JUDGE GREEN: We are familiar with the facts of your Brief. Go
18	right to the issues.
19	MR. MARSH: Thank you, Your Honors. I think we largely agree on
20	the facts here, both the Patent Office and the patent Applicant. Karpe
21	discloses or the Patent Office says it discloses postprandial elevation of
22	plasma triglycerides that are more closely linked to, commonly, heart
23	disease. Beeley discloses exendin with respect to food intake and the
24	reduction of plasma lipids, but it is absolutely silent on triglycerides, and
25	
26	

1 also discloses with respect to a cardiac effect. And we agree also that 2 triglycerides are a component of blood plasma. 3 I think this comes down very much to a legal issue as to the combination in a case where neither of the primary references, inherently or 4 5 otherwise, teach the claimed invention. So I think it's important to go to what the claims say. And the claims in this case say "a method of lowering 6 7 triglyceride levels in a subject in need thereof." Nowhere in the cited art is 8 there a subject identified in need of lowering triglyceride levels. Nowhere 9 do they identify subjects having elevated postprandial triglyceride levels, at 10 least with respect to an exendin treatment, and then administering to that 11 subject a therapeutic effective amount of the exendin. 12 So when you look at the law associated with inherency, inherency 13 cannot be used to combine 103. Here we have -- it's not even arguably 14 inherent because there is teaching that's of record that says cross-drugs, 15 particularly in a food intake situation, you know, triglycerides are not always 16 reduced. Just because blood plasma lipids go down, triglycerides don't 17 necessarily go down. That's not refuted anywhere on the record. That's 18 clear on the record. So I think very much here we've got a situation where 19 we have a question, really, of law, not a question of fact. 20 We have a patient in need thereof. We have two references that can at 21 best be combined if you take an inherent inverted converse reading of them. 22 Neither of them really are inherent, just a matter of law, is not without fail. 23 There is no teaching that just because blood plasma levels come down --24 lipid levels come down, that triglycerides come down. Actually, the 25 teaching is exactly opposite of that.

1	JUDGE GREEN: Where is it opposite of that?
2	MR. MARSH: Well, if you look to the record, Bravata
3	reference, Bravata says in a food take situation food intake situation it
4	doesn't and it says it doesn't necessarily result in the lessening of
5	triglycerides.
6	JUDGE PRATS: But doesn't that mean that your claimed method will
7	not necessarily result in lowering triglycerides?
8	MR. MARSH: Two different parts. That's a good question. One is
9	what the art taught. The art taught in a food intake situation, as opposed to a
10	postprandial situation, that triglycerides would not necessarily be reduced.
11	Here we are postprandial, post-food, as opposed to pre-food. We have a
12	situation where it's been shown with the experimental data that the
13	triglycerides go down. So two different sort of situations. The art is
14	teaching the same sort of situation as Beeley, i.e. it's a food reduction
15	situation as opposed to a post-feeding situation.
16	JUDGE GREEN: Are you talking about when you're administering
17	the exendin?
18	MR. MARSH: Yes.
19	JUDGE GREEN: Because does your claim really I mean, you
20	identify and then you administer, but you have a comprising claim. I mean,
21	is there really a time situation set forth by your claim? I mean, you could
22	have identified a week before and then put on the therapy.
23	MR. MARSH: You're correct. The claim does not have a time
24	limitation in there. Notwithstanding that, you've identified that they need
25	triglycerides lowered, and I think where you're going to, is the claim
26	

1 enabled? But one of the questions -- we haven't had that rejection, you 2 know, presented, so it's very hard as an Appellant to respond to a rejection 3 that's not there. 4 What the specification teaches, we have examples, is that when you 5 give exendin in the postprandial situation, the triglycerides are lowered. It's 6 very hard to argue that it's not all the occasions, because the evidence that's 7 in the record shows that it does. 8 JUDGE LEBOVITZ: What is the inherency issue that you referred to? 9 10 MR. MARSH: I think there's a couple of inherency issues. The first 11 inherency issue is they think about it as the blood plasma. Just because lipid 12 levels are going down as a whole, that necessarily, without fail, means that 13 triglycerides are also lowered as a component of blood plasma. And I think 14 that the evidence in the record shows that you can have one group go up, one 15 group go down. Just because the grand total goes down, it doesn't mean that 16 an individual component -- and I think there's nothing in Karpe, Beeley, or 17 any of the other cited references that says this component goes down. 18 JUDGE LEBOVITZ: But once you have a reason to administer the 19 drug to patients, wouldn't it inherently follow that the triglyceride levels are 20 lowered? 21 MR. MARSH: Let me try and parse it out. And I apologize if I don't 22 fully follow your question, and please redirect me if I'm on the wrong base. 23 There is no reason identified for lowering the triglycerides in the art, you 24 know, in the cited art. You know, lowering triglycerides is a good thing. I

25

know that that's out there as a medical thing.

1 JUDGE LEBOVITZ: Okay. That was my question. 2 MR. MARSH: Okay. 3 JUDGE LEBOVITZ: You said there's no reason for lowering --4 MR. MARSH: For using --5 JUDGE LEBOVITZ: -- triglycerides in the art. Let me just finish the 6 question. 7 MR. MARSH: I apologize. 8 JUDGE LEBOVITZ: So where does the claim require that the 9 triglycerides be lowered? Or to put more clearly, where does the claim 10 require an appreciation that the triglycerides are lower? 11 MR. MARSH: Two parts in the claim. The first part is that lowering 12 triglyceride levels in a subject in need thereof, and that's the right on point of 13 the <u>Jansen v. Rexall</u> case, so --14 JUDGE LEBOVITZ: Yes, but that -- that's what I'm alluding to, but 15 there is a Board case Ex parte Batteux. I'm not sure I'm pronouncing it 16 correctly, but in that case, that case tells us -- we don't follow that case 17 because that case was a limitation case where there was a presumption of 18 validity. We do broadest reasonable interpretation and we would more go 19 along Perricone -- cases. I know that was a 102. 20 MR. MARSH: I think one is we were 103. So we're not in a 102 21 situation. Two is I'm not familiar with that Board case. But the -- I don't 22 know if it's a precedential case from a Board case. 23 JUDGE LEBOVITZ: It was an informative case. 24 MR. MARSH: Yeah. So --25 JUDGE LEBOVITZ: And it does distinguish Rexall v. Jansen.

1	MR. MARSH: Yeah. Let's break I was going to break into the
2	second part of the claim, then I'll come back to yours. The claim also has a
3	second part to it where it talks about wherein said subject's postprandial
4	triglyceride levels are lowered. So it's not just a patient in need thereof.
5	You have the effect of actually lowering. And there isn't teaching in the art
6	of exendin lowering triglycerides in a postprandial situation.
7	JUDGE GREEN: But there's no positive step of measuring
8	triglyceride levels after this therapy?
9	MR. MARSH: But there's a
10	JUDGE GREEN: I'm just asking. There is no positive step, right,
11	wherein or whereby that clause? Since this is a result, but there is no
12	positive step of, you know, measuring the subjects' postprandial triglyceride
13	levels to determine that they are lowered?
14	MR. MARSH: Can I break it down into two different bits? I think
15	the wherein clause requires that they are lowered. If they're not lowered,
16	you're outside the scope of the claim. So the measuring goes to the
17	infringement part of it, not going to what's within and out of the scope of the
18	claim. So, you know, because it says the wherein said are lowered. So if
19	they're not lowered, then you're outside the scope of the claim and you're not
20	covered by this activity. And art pertinent to that would not apply. I'm not
21	sure if I'm answering your question.
22	JUDGE GREEN: But if you have 100 patients that you administer the
23	exendin to and 50 of them have lower triglyceride levels, wouldn't that still
24	meet that limitation?
25	

1	MR. MARSH: The 50 who have their triglyceride levels lowered by
2	the drug and they're in need thereof, i.e., you've identified that need, are
3	within the scope of the claim and would be. The 50 who don't, are not
4	within the scope of the
5	JUDGE GREEN: Whether you've measured it or not, according to
6	your
7	MR. MARSH: I would
8	JUDGE GREEN: Whether you've determined whether those levels
9	are lowered or not?
10	MR. MARSH: With respect maybe I'm doing a poor job of
11	explaining myself here. I'll try again. And I apologize. The issue is that the
12	ones where their levels are not lowered are not within the scope of the claim.
13	So I could never they would not be it would not be an infringing use of
14	Exendintide, i.e. they would be outside the scope of the claim because their
15	levels are not lowered. So the fact that I measure or don't measure, I think
16	is, with the greatest respect, I think a moot point here.
17	JUDGE GREEN: I understand that, but what if if we have a
18	situation and we have the primary reference and it goes ahead and measures
19	the triglyceride levels and says people with elevated triglyceride levels are
20	more at risk for cardiovascular disease, and then we have a secondary
21	reference that says you can use this compound to treat people who have
22	who are at risk for cardiovascular disease with exendin. So if you combine
23	those two and administer the exendin to people with cardiovascular disease,
24	without any knowledge of your disclosure, if their triglyceride levels are
25	lowered, they now infringe your claim, correct?

26

1 MR. MARSH: Two different things. Let's -- on the claim it says in 2 need thereof. So the patient population there -- there's got to be a patient 3 population under <u>Jansen v. Rexall</u>, and I take your point about where the 4 Board is on --5 JUDGE GREEN: But these -- how you determine which patients are 6 in need or thereof are by identifying the subjects having elevated 7 postprandial triglyceride levels, which is what the primary reference does, 8 correct? 9 MR. MARSH: And also you have in the first step of Claim 1 10 identifying a subject having elevated postprandial triglyceride levels. So 11 you're doing that as part of --12 JUDGE GREEN: But that's taught by the first reference, correct, the, 13 I guess --14 JUDGE PRATS: Karpe. 15 JUDGE GREEN: -- the Karpe reference? 16 MR. MARSH: The Karpe reference says -- not with respect to this 17 drug, not with respect to --18 JUDGE GREEN: Not with respect to this drug. 19 MR. MARSH: -- this drug at all. It just says that -- it suggests -- and 20 it's somewhat muddied on what it suggests, but it suggests that, at least the 21 most aggressive reading of it, it suggests that postprandial elevation of 22 plasma triglycerides is closely linked to coronary heart disease. It does 23 suggest that. So given that -- but it is absolutely silent on how to get from 24 there to our claimed invention. It doesn't --25 JUDGE PRATS: If I may? You have two steps.

1	MR. MARSH: Yeah.
2	JUDGE PRATS: You have identifying elevated postprandial
3	triglyceride levels, and that is suggested by Karpe. You have administering
4	exendin compound or exendin and agonists, and that is taught suggested in
5	the art to treat the very patients that are identified in the first step by the
6	Karpe reference. So is there any positively recited step of your process that
7	is not suggested by these references?
8	MR. MARSH: There is the positively recited step that is the
9	combination. You can't with the greatest respect, you can't dissect the
10	claim quite that way, because you have to read the claim as a whole. The
11	claim as it's a whole, is combining identifying the triglyceride patient with
12	the treatment of that patient with Exendintide to reduce the levels of
13	triglycerides. Beeley is silent, as is Karpe, on the effect.
14	JUDGE PRATS: So you're saying your purpose is different, but
15	actually the prior art says do the same thing but for a different purpose?
16	MR. MARSH: And the prior what I am saying is that the prior art
17	does never identify a patient in need thereof of doing this, i.e., you know, not
18	all patients that you give a Exendintide to will be given Exendintide for, you
19	know, the lowering triglycerides. Some will have perfectly normal
20	triglycerides.
21	JUDGE PRATS: Right. But your identification step is suggested by
22	the prior art to identify individuals that have coronary heart disease or at risk
23	of coronary heart disease, and then the next reference says treat patients with
24	coronary heart disease by administering exendin. So both of the positively
25	

- 1 recited steps, as I see it, are suggested by the art and are suggested not
- 2 separately, but suggested be both performed as a single process.
- 3 MR. MARSH: I respectfully disagree. I think there's a -- for the
- 4 following reason. One is that Beeley suggests cardiac risk as one -- as
- 5 opposed to --
- 6 JUDGE PRATS: As does Karpe.
- 7 MR. MARSH: As does Karpe. And what we have here is, when you
- 8 take it as a -- neither of them identify the patient population. Exendin, for
- 9 instance, has a multitude of uses, you know, out there now known. Neither
- of them identify the population that is here at issue. Neither of them identify
- 11 a population that is a -- for use with Exendintide of a triglyceride-raised
- 12 population.
- JUDGE GREEN: Would the population of the Karpe reference,
- 14 cardiovascular risk, wouldn't that encompass -- isn't that a larger population,
- 15 but would still encompasses your population?
- MR. MARSH: The -- it is a population. But what Karpe doesn't do,
- 17 Karpe doesn't tie it to the use of Exendintide. Nothing ties the use of
- 18 Exendintide to a triglyceride population, nothing.
- 19 JUDGE GREEN: I think we have your argument, so now if you'll --
- 20 we're past about 15 minutes. If you want to --
- 21 MR. MARSH: I appreciate the --
- JUDGE GREEN: Okay. Wait, we have one more question.
- JUDGE LEBOVITZ: I just want to clarify one thing for the record.
- 24 The reference that I was referring -- the decision I was referring to, Ex parte

25

1 B-a-t-t-e-u-x, which was an informative decision, Appeal Number 2007-0622. 2 3 MR. MARSH: I appreciate the clarification, Your Honor. 4 JUDGE GREEN: Okay. We'll -- your rebuttal. 5 Do you mind spelling your name for the court reporter? 6 **EXAMINER SPECTOR:** Both? 7 JUDGE GREEN: Yeah, would you, please? 8 EXAMINER SPECTOR: I'm Lorraine, L-o-r-r-a-i-n-e, Spector, 9 S-p-e-c-t-o-r, known to all of you as Lorie. 10 Good morning. If it please the Board, the Attorney has said that we 11 agree on the teachings of the references. That is true. Where we're 12 disagreeing is on what the rejection is. Applicants have argued repeatedly 13 on the record that the rejection falls on the basis of inherency and lack of 14 expectation of success. Our interpretation of the rejection is -- if I can get to 15 the right pages in my notes -- that Karpe teaches elevated postprandial 16 triglycerides are related to a higher risk of corony artery disease. Applicant 17 is correct that Karpe does not teach the use of exendin to lower those 18 triglycerides. However, Beeley teaches the lowering of plasma lipid levels 19 with exendin and the Merck Manual, which was cited by the Examiner, 20 teaches that lipid levels are made of two primary components, cholesterol 21 and triglycerides. So the rejection was on the basis that given those three 22 teachings, it would have been obvious to measure triglycerides and on the basis of those triglycerides to administer exendin. 23 24 JUDGE LEBOVITZ: How would you know whether the exendin

25

would lower the levels of all of those components? I mean --

1	EXAMINER SPECTOR: You wouldn't.
2	JUDGE LEBOVITZ: I think he mentioned only two or three, so
3	how would you have any idea of that?
4	EXAMINER SPECTOR: Well, it's two. And we're going more on if
5	there are only two species within the genus, it is obvious to try both of them.
6	JUDGE LEBOVITZ: So it's obvious to try?
7	EXAMINER SPECTOR: So it's obvious to try
8	JUDGE LEBOVITZ: But don't you have to have a reasonable
9	expectation of success to make it obvious to try?
10	EXAMINER SPECTOR: Well, I think with a genus of two, we have
11	a reasonable expectation of success.
12	JUDGE LEBOVITZ: Why? I mean, what's telling you it would work
13	on one and not the other?
14	EXAMINER SPECTOR: Nothing in particular. I think we're also
15	relying on the KSR decision, which held that a person of ordinary skill has
16	good reason to pursue the known options within his or her technical grasp.
17	JUDGE LEBOVITZ: Was it predictable?
18	EXAMINER SPECTOR: Okay.
19	JUDGE LEBOVITZ: And what would be
20	EXAMINER SPECTOR: If this leads to anticipated success. I guess
21	what we're saying here is you had a 50 percent chance, and
22	JUDGE LEBOVITZ: I'm not sure
23	EXAMINER SPECTOR: that's a reasonable expectation.
24	JUDGE PRATS: If I may, I'm not sure I understand what you mean
25	about you have a 50 percent expectation of success. You have Appellants
26	

- 1 have come in with 1, 2, 3, 4 -- well, a number of references that say you
- 2 don't have -- that it's unpredictable as to whether you're going to get
- 3 triglyceride level reduction when you -- in therapeutic methods. So in this
- 4 case, it seems to me, that wouldn't -- I mean, where's your unexpected
- 5 success, you know, when taken in light of those references?
- 6 EXAMINER SPECTOR: I assume you mean where ours reasonable
- 7 expectation of success?
- 8 JUDGE PRATS: What did I say?
- 9 EXAMINER SPECTOR: Unexpected success.
- 10 JUDGE PRATS: Oh. Reasonable expectation of success. You know,
- 11 you have Bravata, Gaudio, Ödmark as the other references suggesting that
- 12 you're not necessarily going to get triglyceride reduction.
- 13 EXAMINER SPECTOR: Well, a finding under 103 doesn't require a
- 14 necessary expectation of success. It doesn't require absolute certainty of
- success. And I don't think any of the references make a case that you
- wouldn't expect success, they just say they don't know what the outcome's
- 17 going to be.
- JUDGE LEBOVITZ: Well, if you don't know what the outcome is,
- 19 then I think it's unpredictable. But where's the teaching identifying a subject
- 20 having elevated triglyceride levels, postprandial triglyceride levels?
- 21 Because to me that seems a little different. Identifying a population with
- 22 heart disease is not the same thing as identifying a subject having elevated
- 23 triglyceride levels. The two aren't synonymous with each other.
- 24 EXAMINER SPECTOR: They are not synonymous.
- JUDGE LEBOVITZ: They aren't identical populations.

1	EXAMINER SPECTOR: I agree. I think that the combination of the
2	Beeley and the Merck references, specifically the Merck reference which
3	refers to plasma lipids as being cholesterol and triglycerides, and therefore
4	it's obvious to measure them both and see which one correlates. There is
5	also a chance there are three possible outcomes: that one that lipids
6	correlate and triglycerides don't, that triglycerides correlate and lipids don't,
7	or that both correlate. So we have a two-thirds expectation of success now.
8	JUDGE LEBOVITZ: But I'm talking about identifying a subject with
9	those elevated levels. Because identifying someone with heart disease is,
10	again, defining a larger population. It's not doing that positively recited
11	feature in the claim.
12	EXAMINER SPECTOR: Well, Karpe specifically says that elevated
13	postprandial triglycerides are associated with a higher risk of coronary artery
14	disease.
15	JUDGE LEBOVITZ: Okay. So you're so Karpe teaches that?
16	EXAMINER SPECTOR: Karpe does teach that.
17	JUDGE LEBOVITZ: Karpe does teach identifying a subject?
18	EXAMINER SPECTOR: Right. And if I can, there was one point I
19	wanted to make about the issue of postprandial, that during the prosecution,
20	whether it's right or wrong, the Examiner and the Applicant agreed to adhere
21	to Karpe's definition, which is found on page 301, where Karpe used six to
22	eight hours after a large high-fat meal. Okay. Karpe specifically says "It
23	has been suggested that postprandial elevation of plasma triglycerides is
24	more closely linked to CHD, than the fasting level. Patch, et al. found that
25	plasma triglycerides measured six to eight hours after a large high-fat meal
0.0	

1	were highly discriminative for CHD." They also go on in the same
2	paragraph to say "furthermore, we recently found the plasma triglyceride
3	concentration measured six hours after a mixed meal" so it didn't have to
4	be a high-fat meal "was associated with signs of early atherosclerosis in
5	men."
6	And the final portion of Karpe I wanted to read you is, of course, in
7	the last paragraph where it says "The present study confirms previous
8	observations that plasma triglycerides measured late in the postprandial state
9	well beyond the peak level are discriminative for CHD in contrast to fasting
10	plasma triglycerides." So I think Karpe clearly points you to measuring
11	plasma triglycerides in the postprandial state, and specifically says in the late
12	postprandial state. And the early part of the paper seems to indicate that the
13	prior art has recognized six to eight hours as being the postprandial state.
14	Let's see. Okay. The other point I want to make is that through the
15	written record and in some of the oral arguments, that Appellants are
16	repeatedly trying to reframe the rejection as to rendering obvious treatment
17	of obesity and not to elevated levels of triglycerides as addresssed in the
18	rejection. But obesity is not the issue here. The issue here is coronary artery
19	disease and, specifically, measurement of triglycerides.
20	Applicant has made the case that patients with cardiac risk do not
21	inherently have elevated triglycerides, and this is reading into their argument
22	of inherency. Once again, I would remind you that we are not arguing any
23	inherency in our rejection or any of our arguments, and we've stated
24	repeatedly on the record that that is so, that what we are doing is combined
25	

1

2 would be motivated to combine them to arrive at the claimed invention. 3 JUDGE LEBOVITZ: And that was one of the issues that we wanted to clarify, was the reason why --4 EXAMINER SPECTOR: Yes, that's an important issue to clarify. 5 6 The issue is not inherency; it is obviousness, that what we find is that Karpe 7 leads you to an association of triglycerides with coronary artery disease, that 8 Beeley says that you can lower lipid levels with exendin, and that Merck 9 elucidates that plasma lipids are cholesterol and triglycerides. So what we 10 have is two possible species, okay, and -- at first I said there was a 50 11 percent expectation of success. I've now amended it to 66 percent because I 12 think we have three possibilities. One is that the triglycerides are elevated; 13 one is that the cholesterol is elevated, and the third is that they're both 14 elevated. So in two of three you would arrive at this method, which now 15 gives us a 66 percent chance of success. 16 JUDGE PRATS: This says, though -- let me ask it another way. Why 17 don't we need to address the inherency issue, because there appears to be no 18 suggestion in the prior art that exendin actually reduces postprandial 19 triglyceride levels, and that is a positively recited claim on the face in -- in 20 all of the independent claims. 21 EXAMINER SPECTOR: That's true, but this is -- this is not a 102 22 where we're relying on inherency. What we're saying is that there are two 23 possible species suggested by the prior art and it's obvious to try both of 24 them. There is no inherency there. It's an obvious to try, with a more than 25 reasonable expectation of success. 26

references, so that one having the references hung on the wall of the lab

1	And if the Board has no further questions for me, I think I've made the
2	points I came to make.
3	JUDGE GREEN: Okay. Thank you.
4	MR. MARSH: Thank you. I think the Judges made a number of the
5	points that I would have made in my rebuttal, so I'm going to keep this short,
6	unless there are additional questions.
7	I think that the record as a whole shows that inherency is used literally
8	in the words in many of the rejections, the records in front of the Board. I'll
9	leave that to the Board's assessment of that.
10	It is I agree, it is not in an obesity case. I think we've never said it's
11	an obesity case. It's a case related to lowering triglycerides. That is what it's
12	all about. The claim says that. The claim doesn't have the word obesity in
13	it. That's completely and utterly I'm not quite sure where that came from,
14	so I just wanted to say that the claim is what the claim is, and I don't see the
15	word obesity in the independent claims, so. So those are really the points. I
16	think it is, as many as the discussions parsed out during the court, a
17	question of
18	I also have some concerns with the, to say the least, with the 50
19	percent, 60 percent, whatever percent it is. It's unpredictable art. You know,
20	we're not in a situation where we're tossing a coin and 50 percent of the time
21	it's there are multiple components to plasma lipids. There are not just the
22	two. And I don't think you can say just because the Merck index says there
23	are two major components, that a lowering of plasma lipids necessarily,
24	without fail, is going to end up being triglycerides. And that appears on our
25	reading of the record to be what the Patent Office the Examiner is saying.

1	JUDGE GREEN: Any other questions?
2	Okay. Thank you.
3	MR. MARSH: Thank you very much for your time.
4	JUDGE GREEN: If you could answer any questoins that the court
5	reporter may have regarding spellings, I would appreciate that.
6	MR. MARSH: Absolutely. Just you can always e-mail me.
7	(Whereupon, the proceedings, at 9:31 a.m., were concluded.)
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	
26	